DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 7, 2016

Intuit Medical, LLC
Jack Griffis
Vice President, Research & Development
6018 Eagle's Rest Trail
Sugar Hill, GA 30518

Re: K123264
Trade/Device Name: DK-PTCA Balloon Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: October 17, 2012
Received: October 18, 2012

Dear Mr. Griffis:

This letter corrects our substantially equivalent letter of January 16, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123264

Device Name: *DK-PTCA* Balloon Catheter

Indications for Use:

The Intuit Medical, LLC, DK-PTCA Balloon Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123264

Intuit Medical, LLC

510(k) Summary

510(k) Number: K#123264

JAN 16 2013

Date Prepared: January 7th, 2013

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
Intuit Medical, LLC
6018 Eagle's Rest Trail
Sugar Hill, Georgia 30518

B. Company Contact:
Jack Griffis
Vice President, Research & Development
(404) 583-6889 (direct)
jgriffis@intuitmedical.com

C. Device Information:
Trade Name: *DK-PTCA* Balloon Catheter
Common Name: Rapid Exchange Balloon Angioplasty Catheter

D. Classification: Percutaneous Transluminal Coronary Angioplasty Catheter
LOX, 21 CFR 870.5100(a)

E. Predicate Device(s):
Glider™ PTCA Balloon Catheter, K111544
EMPIRA™ & EMPIRA™ NC Balloon Catheters, K110133

F. Physical Description:
The DK-PTCA Balloon Catheter is a torqueable, rapid-exchange, percutaneous transluminal coronary angioplasty catheter. The device is compatible with commonly used accessories including standard 0.014" coronary guide wires and 6F guide catheters (MIN inner diameter of 0.074"). Catheter working length is approximately 142cm.

The distal end of the catheter has a semi-compliant balloon that expands to known diameters and lengths at specific pressures. The balloon has two radiopaque markers to assist with positioning. The proximal end of the device is a common PTCA catheter design consisting of a hypo-tube connected to a plastic hub and strain relief and which assists with torque transmission. The hub is used to inflate the balloon and the luer connector is compatible with standard inflation devices. A second lumen within the catheter, intended for guidewire use, extends from the rapid exchange port to the distal tip. The DK-PTCA Balloon Catheter is supplied sterile and intended for single use.

G. Indications for Use:
The DK-PTCA Balloon Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:
The DK-PTCA Balloon Catheter is substantially equivalent to the predicate devices in intended use, indications for use, fundamental scientific technology, and important performance specifications. The device was subjected to the following performance tests according to FDA Guidance *Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (September 8, 2010):*

- Dimensional Verification
- Balloon Preparation, Deployment & Retraction
- Flexibility & Kink
- Balloon Rated Burst Pressure (RBP)
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation
- Catheter Bond Strength
- Tip Pull Test
- Torque Strength
- Radiopacity
- Biocompatibility Testing in Compliance with the ISO 10993-1 and the FDA Bluebook Memorandum (G-95)
    - Cytotoxicity
    - Sensitization (Guinea Pig Maximization)
    - Irritation and (Acute) Systemic Toxicity
    - Hemocompatibility (both complement activation and *in-vivo* thrombo-resistance)
    - Genotoxicity
    - Material-mediated Pyrogenicity

No new questions of safety or effectiveness were identified during device testing; therefore, the DK-PTCA Balloon Catheter is considered substantially equivalent to the predicate devices.

Jack Griffis
Vice President, Research & Development

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